

## Anexa 58, Centrifugă cu spălare automată a celulelor

### ROTOLAVIT II cu rotor 1017-A, Andreas Hettich, Germania

Parametri solicitati	Parametri oferiti
<p>Centrifugă pentru teste serologice și spălare a celulelor din sânge Capacitate: rotor inclus pentru 10-12 eprubete de 3 ml (10x75 mm)</p> <p>"RPM: setabil, 0 - 3500 rpm, RCF: setabil "</p> <p>Sistem de blocare a capacului în timpul funcționării. Protecție la debalansare. Memorie pentru ≥ 20 programe de lucru, minim 10 programabile de utilizator Program preinstalat pentru mentenanță/curățare a centrifugii Pași disponibili pentru programare: umplere, centrifugare, decantare, agitare. Dozare automată a soluției fiziologice Dotată cu port pentru evacuarea deșeurilor Dotată cu pompă pentru soluție fiziologică și senzor de flux Interfața cu utilizatorul: ecran tactil color Afișare pe ecran a timpului rămas și etapelor programului actual Nivel Zgomot ≤50 dB Alimentare: 210-240 V 50 HZ Dimensiuni: L,A,H ≤ 500 mm Tip motor: fără perii. Capacul sa fie transparent sau dotat cu fereastra sau alta cale de acces, necesar pentru efectuarea procedurii de verificare periodica a turațiilor, conform normelor și standardelor în vigoare. Certificat conformitate european, IVD.</p>	<p>Centrifugă pentru teste serologice și spălare a celulelor din sânge Capacitate: rotor inclus cod 1017-A pentru 12 eprubete de 3 ml (10x75 mm), inclusiv adaptoare cod 1019 "RPM: setabil, 0 - 3500 rpm, RCF: setabil "</p> <p>Sistem de blocare a capacului în timpul funcționării. Protecție la debalansare. Memorie pentru 31 programe de lucru, 24 programabile de utilizator si 7 presetate Program preinstalat pentru mentenanță/curățare a centrifugii Pași disponibili pentru programare: umplere, centrifugare, decantare, agitare. Dozare automată a soluției fiziologice Dotată cu port pentru evacuarea deșeurilor Dotată cu pompă pentru soluție fiziologică și senzor de flux Interfața cu utilizatorul: ecran tactil color Afișare pe ecran a timpului rămas și etapelor programului actual Nivel Zgomot 49 dB Alimentare: 210-240 V 50 HZ Dimensiuni: L,A,H 330 x 480 x 280 mm Tip motor: fără perii. Capacul este dotat cu fereastra, necesara pentru efectuarea procedurii de verificare periodica a turațiilor, conform normelor și standardelor în vigoare. Certificat conformitate european, IVD.</p>

WASH CENTRIFUGE

# — ROTOLAVIT II

## USER FRIENDLY SEROLOGY SOLUTIONS

The ROTOLAVIT II cell washing system facilitates routine tasks in transfusion centre laboratories. It was developed for cross-matching, as well as antibody search and differentiation, and for cell washing in TB tests. Its modern touch screen enables the simple and rapid input of up to 24 different programs. The centrifuge has a small footprint and delivers reliable results at low costs for consumables.



## — HIGHLIGHTS

- max. RPM: 3,500 min<sup>-1</sup>
- max. RCF: 1,438
- max. Capacity: 24 x 5 ml
- automatic cell washing system for serological testing
- choice of 2 rotors 12-place or 24-place
- IVDR-conform according to regulation (EU) 2017/746
- maximum noise level of ≤ 49 dB (A)
- easy operation with intuitiv touch screen
- 24 program memories for more individuality
- 7 pre-installed application programs

## — FEATURES



- metal housing and lid
- viewing port in the lid
- one-hand lid lock
- lid dropping protection
- emergency lid lock release
- brushless drive
- error display
- imbalance switch-off
- color touch screen with actual values of all parameters
- auditory message after completion of the centrifugation run

## TECHNICAL DATA

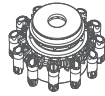
<b>ROTOLAVIT II</b>	
voltage	100 – 240 V 1 ~
frequency	50 – 60 Hz
consumption	144 VA
emission, immunity	EN/IEC 61326-3-2 / FCC CFR47 part 15, ed 2015-04-21 (e-CFR) class B
max. capacity	24 standard tubes (10 x 75 mm or 12 x 75 mm)
max. RPM	3,500 min <sup>-1</sup>
max. RCF	1,438
radius (both rotors)	105 mm
dimensions (HxWxD)	330x480x280 mm
weight	approx. 24.5 kg
max. noise level	≤ 49 dB (A)
<b>Cat. No.</b>	<b>1008-00</b>

The ROTOLAVIT II is not available in all countries.

## AVAILABLE ROTORS

<b>SWING-OUT ROTORS</b>	angle	max. RPM	max. capacity	Cat. No	page
 swing-out rotor, 12-place	45°	3,500 min	12 x (10x75 mm* or 12x75 mm) * Tubes requires adapter No. <b>1019</b>	<b>1017-A</b>	3
 swing-out rotor, 24-place	45°	3,500 min	24 x (10x75 mm* or 12x75 mm) * Tubes requires adapter No. <b>1019</b>	<b>1018-A</b>	3

— SWING-OUT ROTOR, 12-PLACE | 1017-A



<b>Rotor</b>	
max. RPM   max. RCF	3,500 min <sup>-1</sup>   1,438
max. capacity	12 x 5 ml
angle   max. noise level	45°   49 dB (A)
<b>Cat. No.</b>	<b>1017-A</b>

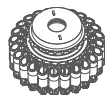


<b>Vessels</b>	
capacity in ml	3      5
Ø x L in mm	10 x 75      12 x 75
max. RCF <sup>2)</sup>	1,438      1,438
radius in mm	105      105
<b>Cat. No.</b>	<b>tubes<sup>2)</sup></b>



<b>Adapter</b>	
boring Ø x L in mm	-      -
vessels per rotor	12      12
<b>Cat. No.</b>	<b>1019 (12 pcs.)      -</b>

— SWING-OUT ROTOR, 24-PLACE | 1018-A



<b>Rotor</b>	
max. RPM   max. RCF	3,500 min <sup>-1</sup>   1,438
max. capacity	24 x 5 ml
angle   max. noise level	45°   49 dB (A)
<b>Cat. No.</b>	<b>1018-A</b>



<b>Vessels</b>	
capacity in ml	3      5
Ø x L in mm	10 x 75      12 x 75
max. RCF <sup>2)</sup>	1,438      1,438
radius in mm	105      105
<b>Cat. No.</b>	<b>tubes<sup>2)</sup></b>



<b>Adapter</b>	
boring Ø x L in mm	-      -
vessels per rotor	24      24
<b>Cat. No.</b>	<b>1019 (12 pcs.)      -</b>

2) Please note that the RCF values indicated refer only to rotor performance. The max. permissible RCF of tubes used should be verified with the individual manufacturers. The max. RCF for glass tubes annotated with footnote 2) is 4,000.

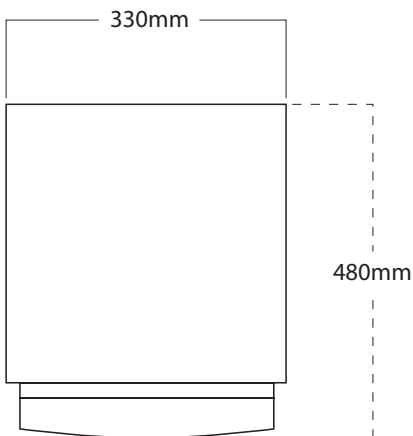
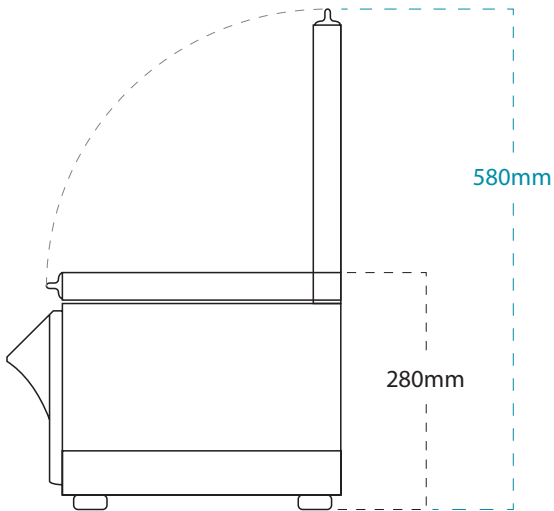
CERTIFICATES / REGISTRATIONS



according to regulation (EU) 2017/746



DIMENSIONS



## EG-Konformitätserklärung EC Declaration of conformity

des Herstellers

of the manufacturer

Hettich AG • Seestrasse 204a • 8806 Baech • Switzerland  
CHRN: CHRN-MF-20000044

Hiermit erklären wir in unserer Verantwortung, ohne Mitwirkung einer benannten Stelle, dass das bezeichnete Gerät:

We hereby declare under our responsibility without involvement of a notified body that the designated device:

Geräteart **Waschzentrifuge**  
Name **Rotolavit II (1008-00)**  
Basic UDI-DI **07640173551008-0029**  
GMDN **35901**  
Klassifizierung **In-Vitro Diagnostikum, Klasse A (Anhang VIII, Regel 5)**  
Gemäss **Verordnung (EU) 2017/746 Anhang IX**  
Ab Seriennr. **0002313**

Type of device **Cell Washer Centrifuge**  
Name **Rotolavit II (1008-00)**  
Basic UDI-DI **07640173551008-0029**  
GMDN **35901**  
Classification **In-Vitro Diagnostic, class A (Annex VIII, Rule 5)**  
according to **Regulation (EU) 2017/746 Annex IX**  
From serial-no. **0002313**

inklusive des mit dem Gerät konformitätsbewerteten Zubehörs laut Zubehörliste der zugehörigen technischen Dokumentation, den einschlägigen Bestimmungen der Verordnung (EU) 2017/746 über In-Vitro-Diagnostika entspricht.

and its accessories, which are listed in the related technical documentation and whose conformity has been assessed together with the device, complies with the relevant provisions of the Regulation (EU) 2017/746 on in-vitro diagnostic devices.

Das Gerät entspricht auch den anwendbaren Bestimmungen der folgenden europäischen Richtlinien und Verordnungen:

The device also complies to the applicable provisions of the following European directives, ordinances and standards:

- 2006/42/EG über Maschinen (Maschinenrichtlinie)
- 2014/30/EU über elektromagnetische Verträglichkeit (EMV-Richtlinie)
- 2014/35/EU «Niederspannungsrichtlinie»
- 1907/2006/EU REACH - Verordnung
- 2017/821/EU Konfliktminerale - Verordnung
- 2011/65/EU RoHS II – Richtlinie + 2015/863/EU

- 2006/42/EC on machinery (machine directive)
- 2014/30/EC to electromagnetic compatibility (EMC Directive)
- 2014/35/EU «Low Voltage Directive»
- 1907/2006/EC REACH - Regulation
- 2017/821/EU Conflict Minerals - Regulation
- 2011/65/EU RoHS II – Directive + 2015/863/EU

Angewendete einschlägige Normen:

EN ISO 13485:2016; EN ISO 18113-3:2013;  
EN ISO 17664-1:2021; EN ISO 14971:2022;  
EN 61010-1:2020; EN 61010-2-020:2017;  
EN 61010-2-101:2017

Applied relevant standards:

EN ISO 13485:2016; EN ISO 18113-3:2013;  
EN ISO 17664-1:2021; EN ISO 14971:2022;  
EN 61010-1:2020; EN 61010-2-020:2017;  
EN 61010-2-101:2017

Baech, 1st of March 2023



Doris Friedlos  
Geschäftsführerin, Chief Executive Officer



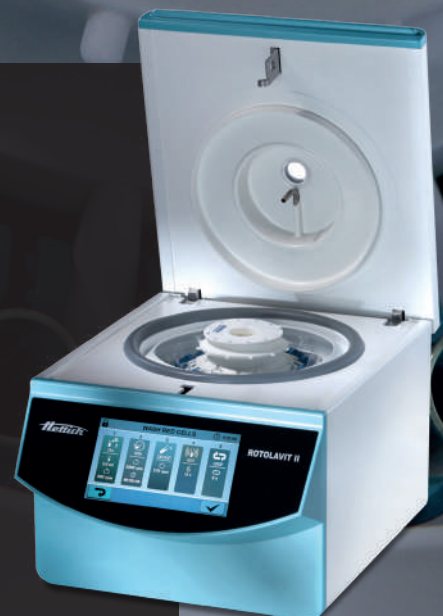
Diese Konformitätserklärung ist gültig von 01.03.2023 bis 28.02.2026

This declaration of conformity is valid from 01.03.2023 until 28.02.2026



## ROTOLAVIT II

User friendly serology solutions



# THE NEW ROTOLAVIT II CELL WASHING CENTRIFUGE

- Developed from your specific requirements

The ROTOLAVIT II cell washing system facilitates routine tasks in transfusion laboratories. In addition to antibody search and differentiation, the ROTOLAVIT II is mainly used for antiglobulin testing. It saves valuable time and effort for the user, especially when compared to the manual method.

In providing reliable and consistent results in all application areas, the valuable experience and customer feedback of the previous model were used. The next generation of the proven ROTOLAVIT model can be operated intuitively via a touch screen. This makes it possible to present processes in an easily understandable and clear manner and to customize them easily to the required application.



» We are impressed by the versatility and the user-friendly design of the new ROTOLAVIT II and are completely satisfied with the quality. «

Interregionale Blutspende SRK AG, Bern, Switzerland

- Good reasons to choose ROTOLAVIT II:

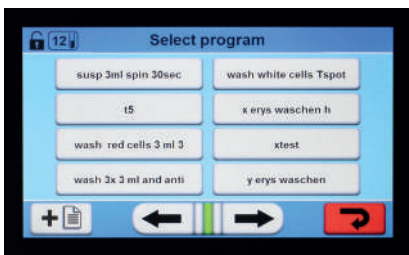
- 1 Innovation you can touch**  
With its large touch screen, the ROTOLAVIT II sets a new standard in user-friendliness – even when wearing gloves.
- 2 Flexible configuration for all customer needs**  
High configurability due to large memory space for own programs.
- 3 Time saving in the laboratory**  
With a top speed of 3,500 RPM, the washing centrifuge is one of the fastest on the market. This accelerates laboratory processes and their efficiency.
- 4 Security through user groups**  
In order to prevent unauthorized or accidental changes, functions such as the calibration of the instrument are only accessible to selected users.
- 5 Quiet operation**  
With a low noise level of only 49 dB (A), the ROTOLAVIT II is a quiet but invaluable part of the lab.



## THE NEW STANDARD IN USER-FRIENDLY OPERATION

- 24 easily manageable independent programs

With up to 24 different program slots, the ROTOLAVIT II can be used for a wide range of laboratory applications. The programs themselves can be retrieved and started with just a few clicks. In addition, the details required during a work process are clearly displayed.



Program overview



Program details



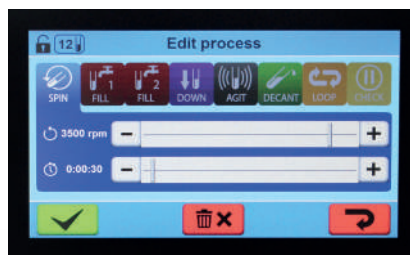
Start program

- Easy configuration of new programs

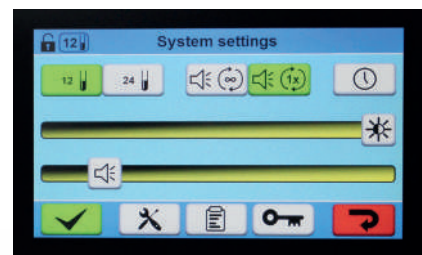
The ROTOLAVIT II allows detailed editing of programs in order to adapt perfectly to every operation in your laboratory. Up to 20 individual processes per program can be adjusted and linked together like building blocks. If required, system settings such as brightness and alarm volume can also be personalized.



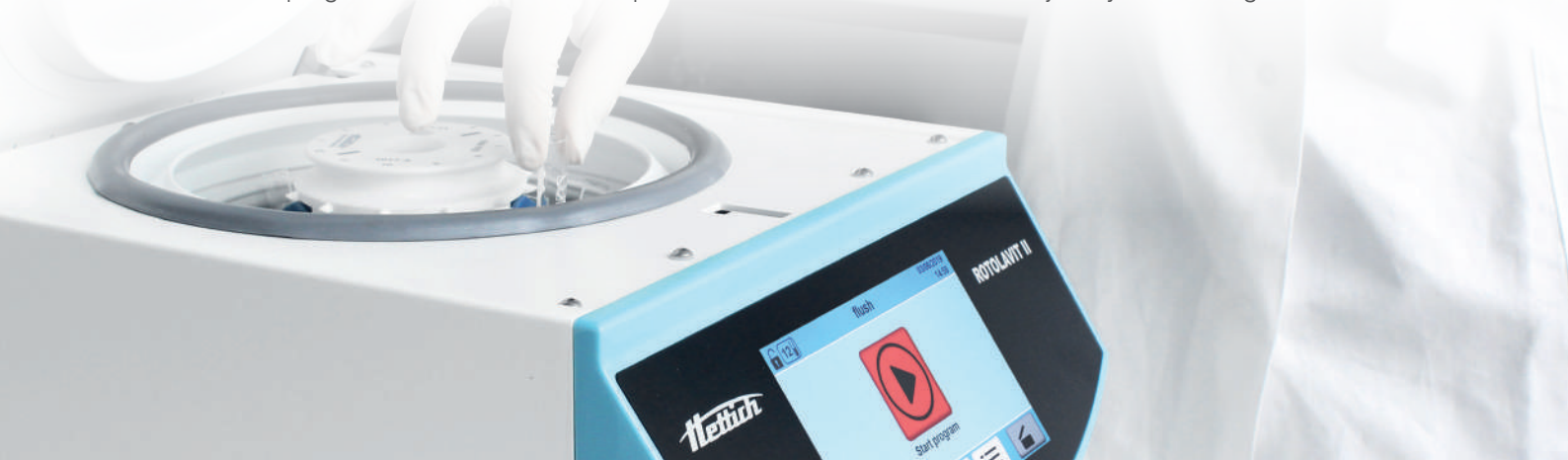
Create new program



Edit processes



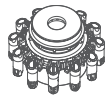
Adjust system settings



# TECHNICAL DATA

		<b>ROTOLAVIT II</b>
voltage		100 – 240 V 1 ~
frequency		50 – 60 Hz
consumption		144 VA
emission, immunity		EN/IEC 61326-3-2 / FCC CFR47 part 15, ed 2015-04-21 (e-CFR) class B
max. capacity		24 standard tubes (10 x 75 mm or 12 x 75 mm)
max. RPM		3,500 min <sup>-1</sup>
max. RCF		1,438
radius (both rotors)		105 mm
dimensions (HxWxD)		330x480x280 mm
weight		approx. 24.5 kg
max. noise level		≤ 49 dB (A)
<b>Cat. No.</b>		<b>1008-00</b>
11 – 30 V 1 ~ / DC 1)		1008-03
consumption		144 VA

— swing-out rotor,  
12-place | **1017-A**

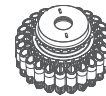


<b>Rotor</b>	
max. RPM   max. RCF	3,500 min <sup>-1</sup>   1,438
max. capacity	12 x 5 ml
angle   max. noise level	45°   49 dB (A)
<b>Cat. No.</b>	<b>1017-A</b>

<b>Vessels</b>		
capacity in ml	3	5
Ø x L in mm	10 x 75	12 x 75
max. RCF <sup>2)</sup>	1,438	1,438
radius in mm	105	105
<b>Cat. No.</b>	<b>tubes<sup>2)</sup></b>	

<b>Adapter</b>		
boring Ø x L in mm	-	-
vessels per rotor	12	12
<b>Cat. No.</b>	<b>1019</b> (12 pcs.)	<b>-</b>

— swing-out rotor,  
24-place | **1018-A**



<b>Rotor</b>	
max. RPM   max. RCF	3,500 min <sup>-1</sup>   1,438
max. capacity	24 x 5 ml
angle   max. noise level	45°   49 dB (A)
<b>Cat. No.</b>	<b>1018-A</b>

<b>Vessels</b>		
capacity in ml	3	5
Ø x L in mm	10 x 75	12 x 75
max. RCF <sup>2)</sup>	1,438	1,438
radius in mm	105	105
<b>Cat. No.</b>	<b>tubes<sup>2)</sup></b>	

<b>Adapter</b>		
boring Ø x L in mm	-	-
vessels per rotor	24	24
<b>Cat. No.</b>	<b>1019</b> (12 pcs.)	<b>-</b>

2) Please note that the RCF values indicated refer only to rotor performance. The max. permissible RCF of tubes used should be verified with the individual manufacturers. The max. RCF for glass tubes annotated with footnote 2) is 4,000. The ROTOLAVIT II is not available in all countries.